

# (12) UK Patent Application (19) GB (11) 2 274 235 (13) A

(43) Date of A Publication 20.07.1994

(21) Application No 9324188.3

(22) Date of Filing 24.11.1993

(30) Priority Data

(31) 08003757 (32) 13.01.1993 (33) US

(71) Applicant(s)

Neo-Life Company Of America

(Incorporated in USA - California)

3500 Gateway Boulevard, Fremont, California 94538,  
United States of America

(72) Inventor(s)

Arianna Carughi

Arthur Furst

Fred G Hooper

John R Miller

(74) Agent and/or Address for Service

Brookes & Martin

High Holborn House, 52-54 High Holborn, LONDON,  
WC1V 6SE, United Kingdom

(51) INT CL<sup>5</sup>

A23L 1/30 1/303 , A23P 1/04 , A61K 35/78

(52) UK CL (Edition M )

A2B BMDE9 B648 B822 B861 B865 B866

A5B BE B30X B30Y B829

U1S S1313 S2411

(56) Documents Cited

GB 2265074 A

GB 2265073 A

GB 2265072 A

GB 2236655 A

(58) Field of Search

UK CL (Edition M ) A2B BMDE1 BMDE9 BMV1 BMV5 ,

A5B BE

INT CL<sup>5</sup> A23L , A23P , A61K

ON-LINE DATABASES, WPI, US CLAIMS

(54) Carotenoid food supplement

(57) A diet supplement composition containing powdered, dried fruits and vegetables rich in alpha-carotene, beta-carotene and lycopene encapsulated in a gelatin capsule in an edible oil.

GB 2 274 235 A

## CAROTENOID FOOD SUPPLEMENT

5

TECHNICAL FIELD

This invention is in the field of food supplements to provide carotenoids at optimal ingestion levels.

BACKGROUND ART

10

Carotenoids are the most numerous group of pigments in nature. They play a critical role in electron transport reactions in plants and are indispensable to healthy functioning of human beings and most animals. The full extent of their role in physiology is not known but experimental evidence indicates that carotenoids may be necessary for proper functioning of the immune system and for protecting tissue from ultraviolet damage. They may reduce chemically induced neoplasia and malignant cell transformation.

15

20

25

Carotenoids are found in fruits and vegetables and an adequate intake of carotenoids, the amount recommended by government agencies and the medical profession, requires ingestion of far more fruits and vegetables than the average diets of persons in the United States and other nations in the Western culture provide. Among better-known carotenoids are alpha-carotene, beta-carotene and lycopene. In addition to being found in fruits and vegetables, beta-carotene is synthesized and the synthetic compound is commercially available. However, there

are hundreds of lesser-studied carotenoids that are found in fruits and vegetables, hereinafter referred to collectively as vegetables, and those lesser-known carotenoids are not present in synthetic preparations such as beta-carotene. The lesser-known carotenoids may play an important (albeit, not fully explored) role in human health as indicated by illnesses or malfunctioning of persons in the Western culture whose diets do not contain enough vegetables. Many of these illnesses or malfunctions are less frequent among persons in populations where diets include large amounts of vegetables. The beneficial effects of lesser-studied or unknown carotenoids may be due to their direct effectiveness in trace amounts or to catalytic or synergistic effects that they exert with the better-known and more thoroughly studied carotenoids such as beta-carotene. Synthetic carotenoids also lack natural distributions of structural differences in their molecules, such as cis- and trans- forms which occur in natural proportions in vegetables. This phenomenon is observed in many ways. For example, when experimental animals are fed either natural or synthetic beta-carotene, liver analyses show at least ten-fold higher levels of beta-carotene in those animals fed the natural form.

#### DISCLOSURE OF THE INVENTION

This invention is a composition useful as a dietary supplement which provides adequate carotenoid ingestion to persons regardless of the inadequacy of their diets with respect to their vegetable intake. The composition of this invention not

only provides adequate quantities of known carotenoids to the diet but it additionally provides the natural level of lesser known and even unknown carotenoids so that the ingestion of a full spectrum of carotenoids in naturally balanced proportions is achieved by supplementing the diet with the composition of this invention.

This invention is an encapsulated composition of powdered vegetable material in an edible oil base. The composition comprises vegetable material that provides alpha-carotene, beta-carotene and lycopene in proportion to each other of about 20 percent to about 40 percent alpha-carotene, about 55 percent to about 80 percent beta-carotene, and about 3 percent to about 20 percent lycopene - the percentages being the weight relationships of those three carotenoids to each other. By providing those carotenoids in that proportion from vegetable materials, the whole array of carotenoids in approximately the balanced composition relationships found in the diet is provided in the composition of this invention. Vegetables that contain high quantities of alpha- and beta-carotene do not contain high quantities of lycopene but they have their own array of other carotenoids. However, those vegetables providing high concentrations of lycopene have an array of carotenoids that are different from the other carotenoids in those vegetables providing high quantities of alpha- and beta-carotene. It has been found that supplying a carotenoid content in the proportions noted above from vegetable sources of those carotenoids provides virtually the entire array of carotenoids in the appropriate

distribution to duplicate the carotenoid ingestion from a balanced diet rich in vegetables. The carotenoids contained in vegetables not only include different carotenoids than those produced synthetically but additionally the carotenoids found in vegetables are superior to synthetic carotenoids because they differ in such things as structural distribution - for example, between cis- and trans- isomers.

Different vegetables contain different carotenoids, and even when they contain the same carotenoids they are in different proportions. For example, carrots are perhaps the best known source of beta-carotene but they contain no lycopene, while tomatoes are a rich source of lycopene but contain very little beta-carotene. Spinach is rich in lutein but has no lycopene and relatively little alpha-carotene. Each vegetable also contains an array of carotenoids that are lesser known, and no vegetable contains all of them.

All carotenoids are contained in the lipid portion of vegetables, so there is an option to use oleoresins extracted from vegetables or powdered, dried vegetables in the compositions of this invention. The decision to use powders or oleoresins is usually based on the cost or availability of oleoresins and the need to adjust the texture or viscosity of the composition. Most carotenoids survive carefully controlled processes such as spray-drying, freeze-drying, powdering, and extraction quite well. The composition of this invention, accordingly, provides a level of alpha-carotene, beta-carotene and lycopene that supplements the usual Western-culture diet to provide the proper intake of those

three carotenoids. In addition, the composition of this invention, by being made from vegetable oleoresins and powdered vegetables, contains a whole array of natural carotenoids - those that have never been studied and those that are not known - and even the known carotenoids are provided in the proper structural distribution that one gets from a balanced diet of vegetables.

#### DETAILED DESCRIPTION OF THE INVENTION

A composition embodying this invention was made having the following ingredients on a weight basis.

<u>Ingredient</u>	<u>Percent</u>
Carrot oleoresin	26.1
Red bell pepper oleoresin	3.0
Peach powder	3.7
Strawberry powder	3.7
Tomato powder	44.9
Spinach powder	14.9
Apricot powder	3.7

The carrot and red pepper oleoresins were obtained by extraction from carrots and red bell pepper bodies respectively. The carrot oleoresin was bright orange, virtually flavorless and readily miscible in water. The red bell pepper oleoresin was a red liquid having the aroma of red bell peppers and very mild red bell pepper flavor.

The powdered material was all obtained by spray- or freeze-drying the noted ingredient and subdividing it to a powder form according to known techniques. The spinach was subjected to low-pressure steaming in a chamber for sufficient time to kill bacteria after which it was freeze-dried and powdered. Dried spinach and dried peach were powdered together to deal with the natural hygroscopicity of peach powder. The carotenoid-containing materials were blended with vegetable oil and lecithin to provide an appropriate texture for encapsulating in a gelatin capsule. The materials were encapsulated in amounts providing 1.5 mg of beta-carotene, 0.5 mg of alpha-carotene and 0.4 mg of lycopene per capsule. The encapsulated materials also supplied other carotenoids that occur naturally in the powders and oleoresins stated in Table 1.

Eleven healthy men and women volunteers between 22 and 52 years of age participated in a study to test if the supplement raised blood carotenoid level. The volunteers had no history of chronic disease, they were taking no medications, they did not smoke, and they were all within 10 percent of ideal body weight for their heights. None of the volunteers had an unconventional dietary pattern, such as vegetarianism. Those volunteers who had been taking carotene-containing supplements stopped doing so two weeks before the study began. All of the volunteers were evaluated for such factors as weight, blood pressure, pulse and temperature at the beginning of the study, two weeks after the beginning of the study, and weekly thereafter.

The study lasted six weeks. During this entire time the diets of the volunteers were self-selected from low-carotenoid foods on a list of foods provided to them. The volunteers were also given a list of carotenoid-containing foods that they were to avoid during the study. The recommended daily diets of the volunteers contained less than 0.4 mg of beta-carotene and alpha-carotene and no lycopene. After two weeks on the low-carotenoid diet the volunteers began taking six of the capsules described above daily. This period was called the supplementation period and it continued for the next four weeks.

A fasting blood sample was collected from each volunteer before the beginning of the study to establish a baseline serum carotenoid level for each subject that was characteristic of his or her own diet and physiologic absorption characteristics for carotenoids. The base-lines were for alpha-carotene, beta-carotene and lycopene only. Blood samples were also collected after two weeks on the low carotenoid diet and weekly during the supplementation period. The samples were collected in accordance with recognized medical techniques, centrifuged to obtain plasma, and analyzed for alpha-carotene, beta-carotene and lycopene by the HPLC method of Bieri et al. Table 2 below reports the data resulting from these tests. The columns headed A are the base-line readings of each volunteer at the start of the test. The columns headed B are the readings after two weeks on the low carotenoid diet at which time the supplementation period began. The columns headed C are the readings at the end of the study - that is, six weeks from the



beginning of the study and four weeks from the beginning of the supplementation period. All reported values are in nanograms per milliliter of serum.

TABLE 2

Volunteer	<u>Beta-Carotene</u>			<u>Alpha-Carotene</u>			<u>Lycopene</u>		
	<u>A</u>	<u>B</u>	<u>C</u>	<u>A</u>	<u>B</u>	<u>C</u>	<u>A</u>	<u>B</u>	<u>C</u>
1	1028	526	1065	422	241	541	728	433	302
2	530	371	1346	169	110	617	275	166	263
3	255	120	365	96	50	238	448	285	400
4	981	571	1170	177	125	428	254	151	238
5	73	21	72	80	20	56	180	126	125
6	156	111	377	44	33	240	437	213	172
7	341	290	1222	129	98	419	292	205	354
8	578	238	578	245	141	236	590	232	216
9	630	435	1254	302	154	495	453	316	343
10	302	169	907	110	79	510	780	284	225
11	154	107	204	43	45	145	856	692	724

From Table 2 it is evident that the data establish the general trend that two weeks on a low carotenoid diet significantly diminished the serum alpha- and beta-carotene levels of the volunteers. The data also establish that the composition of this intervention taken in the four-week supplementation period restored the serum alpha- and beta-carotene levels to the base-line level or in excess of the base-line level for each volunteer.

The data reporting lycopene levels were less conclusive. In general there was a significant reduction in lycopene levels between the base-line levels and the start of the supplementation period but the supplementation period did not restore base-line levels. However, plasma lycopene levels are known to respond slower to changes in dietary intake than alpha- or beta-carotene levels. Lycopene supplementation initially stabilized lycopene plasma levels preventing further decline. It is hypothesized that if the study had been prolonged, gradual increases in lycopene levels to or in excess of the base-line levels would be observed. The weekly tests for serum lycopene bear out this hypothesis. For all but two of the volunteers there was a rising trend in serum lycopene in the final week of the supplementation period. Specifically, the data for the final week were:

	<u>Volunteer</u>	<u>Fifth week</u>	<u>Sixth week</u>
	1	312	302
	2	220	263
20	3	174	400
	4	168	238
	5	20	125
	6	135	172
	7	101	354
25	8	77	216
	9	281	343
	10	274	225
	11	705	724

As noted above, the volunteers were healthy persons before the test started. They were also healthy persons after the test ended. They noticed no subjective changes in their health during the six weeks of the test. It is known that serum carotenoid levels are accurate indicators of the availability of these essential compounds for maintaining good health and that temporary periods of low serum carotenoid levels have no affect on the health of the average individual. However, chronic low carotenoid serum levels may cause health deterioration problems. The study demonstrates that regular ingestion of the composition of this invention will maintain serum carotenoid levels even with a diet that is almost devoid of carotenoids. Its regular use will provide a person with significant ingestion of carotenoids regardless of the vegetable content of that person's usual diet.

## CLAIMS

1. A composition comprising a suspension of powdered materials in an edible oil, said powdered materials comprising a mixture of dried, vegetables, said composition containing alpha-carotene, beta-carotene and lycopene in proportion to one another on a weight basis of from about 20% to about 40% alpha-carotene, from about 55% to about 80% beta-carotene and from about 3% to about 20% lycopene.

2. The composition of claim 1 wherein said edible oil comprises carrot oleoresin.

3. The composition of claim 1 wherein said edible oil comprises red bell pepper oleoresin.

4. The composition of claim 1 wherein said powdered material comprises spinach powder.

5. The composition of claim 1 wherein said powdered material comprises tomato powder.

6. The composition of claim 1 enclosed in a gelatin capsule.

7. The composition of claim 6 wherein said capsule contains from about 500 to about 1000 milligrams of said composition.

8. A composition enclosed in a gelatin capsule comprising from about 150 to about 200 mg of carrot oleoresin, from about 30 to about 50 mg of red bell pepper oleoresin, from about 100 to about 400 mg of powdered, dried tomato, and from about 50 to about 200 mg of powdered, dried spinach.

-13-

**Relevant Technical Fields**

(i) UK Cl (Ed.M) A2B: BMDE1; BMDE9; BMV1; BMV5; A5B: BE

(ii) Int Cl (Ed.5) A23L; A23P; A61K

**Databases (see below)**

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE DATABASES, WPI, US CLAIMS

Search Examiner  
B J GARDNER

Date of completion of Search  
17 FEBRUARY 1994

Documents considered relevant following a search in respect of Claims :-  
1-7

**Categories of documents**

- |   |   |
|---|---|
| <b>X:</b> Document indicating lack of novelty or of inventive step.   | <b>P:</b> Document published on or after the declared priority date but before the filing date of the present application.        |
| <b>Y:</b> Document indicating lack of inventive step if combined with one or more other documents of the same category. | <b>E:</b> Patent document published on or after, but with priority date earlier than, the filing date of the present application. |
| <b>A:</b> Document indicating technological background and/or state of the art.   | <b>&amp;:</b> Member of the same patent family; corresponding document.   |

Category	Identity of document and relevant passages		Relevant to claim(s)
P,X	GB 2265074 A	(YOSHIO TANAKA) See particularly paragraph common to pages 4 and 5 and examples	1 and 6 at least
P,X	GB 2265073 A	(YOSHIO TANAKA) See particularly paragraph common to pages 4 and 5 and examples	1 and 6 at least
P,X	GB 2265072	(YOSHIO TANAKA) See particularly paragraph common to pages 4 and 5 and examples	1 and 6 at least
X	GB 2236655	(YOSHIO TANAKA) See particularly paragraph common to pages 4 and 5 and examples	1 and 6 at least